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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO	
10/015,630	12/17/2001	Francesco Casuscelli	217471US0	7565	
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Garden City, NY 11530			1639		

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)				
Office Action Summany	10/015,630	CASUSCELLI ET AL.				
Office Action Summary	Examiner	Art Unit				
	Jon D. Epperson	1639				
The MAILING DATE of this communication apperent of the second for Reply	ears on the cover sheet with the c	orrespondence address				
A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply if NO period for reply is specified above, the maximum statutory period w - Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	i6(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days ill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONEI	nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133).				
Status						
1) Responsive to communication(s) filed on 11 Ap	oril 2005.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under E	x parte Quayle, 1935 C.D. 11, 45	33 O.G. 213.				
Disposition of Claims						
4)⊠ Claim(s) <u>1-27</u> is/are pending in the application.						
4a) Of the above claim(s) 1-11,21-25 and 27 is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.						
6)⊠ Claim(s) <u>12-20 and 26</u> is/are rejected.						
7) Claim(s) is/are objected to.						
8) Claim(s) are subject to restriction and/or	election requirement.					
Application Papers						
9)⊠ The specification is objected to by the Examiner	r.					
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the o						
Replacement drawing sheet(s) including the correcti		` ,				
11)☐ The oath or declaration is objected to by the Ex	aminer. Note the attached Office	Action or form PTO-152.				
Priority under 35 U.S.C. § 119						
 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 	· · · · · · · · · · · · · · · · · · ·	-(d) or (f).				
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the prior		ed in this National Stage				
application from the International Bureau						
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) Notice of References Cited (PTO-892)		4) Interview Summary (PTO-413)				
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)		Paper No(s)/Mail Date 5) Notice of Informal Patent Application (PTO-152)				
Paper No(s)/Mail Date	6) Other:					

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DETAILED ACTION

Status of the Application

1. Receipt is acknowledged of a Response to a Restriction Requirement, which was dated on April 11, 2005.

Status of the Claims

- 2. Claims 1-27 are pending.
- 3. Applicant's response to the Restriction and/or Election of Species requirements is acknowledged (Applicant elected with traverse Group III, claims 12-20 and 26) and claims 1-11, 21-25 and 27 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim (see Response to Restriction and/or Election of Species below).
- 4. Please note: Applicant's *specifically* elected species (5-cyclopropyl-N-ethyl-3-(2-hydroxyl-5-methylphenyl)-1H-pyrazole-1-carboxamide) was searched and was not found in the prior art. Thus, the search was expanded to non-elected species, which *were* found in the prior art, see rejections below. Also, see MPEP § 803.02 (emphasis added):

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that

anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

5. Therefore, claims 12-20 and 26 are examined on the merits in this action.

Response to Restriction and/or Election of Species

- 6. Applicant's election of Group III (claims 12-20 and 26) with traverse is acknowledged.
- 7. The traversal is on the ground(s) that [1] the Examiner is required to show that the inventions are both "independent and distinct" (e.g., 4/11/05 Response, page 3), [2] Groups I-VI are related and thus should not be divided (e.g., see 4/11/05 Response, page 3, last paragraph), [3] the Examiner has not shown that compounds of formula I can be used on a materially different process of using the product nor has the Examiner shown that the process of using the claimed compounds can be used on another compound with a materially different structure (e.g., see 4/11/05 Response, page 4, paragraphs 1-5), [4] reliance on the supposed classification of the groups of claims does not establish independence and distinctness and even if it did Applicants' contend that the classification is unreliable (e.g., see 4/11/05 Response, page 5), [5] in view of the continued increase of official fees and applicant's limited financial resources, a practice which arbitrarily imposes restriction requirements may become prohibitive and thereby contravene the constitutional purpose to promote and encourage the progress of science and the useful arts and is also not congruent with GATT (e.g., see 4/11/05 Response, pages 5-6), and [6] it is vital to all applicants that restriction requirements issue only with the proper statutory authorization, because patents issuing on divisional applications which are filed to prosecute

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claims that the Examiner held to be independent and distinct can be vulnerable to legal challenges alleging double patenting (e.g., see 4/11/05 Response, page 6).

8. These arguments were fully considered but were not found persuasive. The Examiner contends [1] Applicants' interpretation of "independent and distinct" is not consistent with section 121 of the 1952 Act (e.g., see MPEP § 802.01, "If section 121 of the 1952 Act were intended to direct the Commissioner never to approve division between dependent inventions, the word "independent" would clearly have been used alone ... The law has long been established that dependent inventions (frequently termed related inventions) ... may be properly divided if they are, in fact, "distinct" inventions, even though dependent [i.e., doesn't have to be independent AND distinct as purported by Applicants]", [2] as stated in the restriction requirement, the inventions of Groups I-VI represent patentably distinct methods and/or products with different starting points, different method steps, and different outcomes. Furthermore, the methods and/or products can be separately classified (e.g., see 6/2/04 Restriction, paragraph 1) and represent patentably distinct subject matter (e.g., see paragraphs 3-8). The Examiner also notes that the mere presence of any alleged overlapping subject matter would not constitute a coextensive search because each Group would have to be searched to its full extent and not just to the extent of any overlapping subject matter, which would, as a practical matter, encompass non-overlapping subject matter and hence result in a non-coextensive burdensome search, [3] a sufficient showing has been made with regard to MPEP § 806.05(h) clearly demonstrating that the compounds of formula (I) can be used with a materially different process of using that product including (1) treat a disease, (2) inhibit a kinase in an assay system, (e) product a library

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for screening and (4) product a library as starting materials for producing more complex libraries. No "kinase" activity is required for the "4" element mentioned above as purposed by Applicants. In addition, the Examiner notes that the compounds may also be used for Molluscicidal activity as shown below (e.g., see Nawwar et al. rejection). Finally, it is also noted that MPEP § 806.05(h) may also be satisfied by demonstrating that the process of using the produt as claimed can be practiced with another materially different product, which has also been satisfactorily demonstrated (e.g., see specification, page 6, paragraph 1), [4] the classification system, while not perfect, is the best system that we have and is routinely followed by all Examiners as set forth in the Restriction Guidelines in the MPEP (e.g., see MPEP § 803, Restriction - When Proper, "For purposes of the initial requirement, a serious burden on the examiner may be prima facie shown if the examiner shows by appropriate explanation of separate classification"; see also MPEP § 808.02, "Where the related inventions as claimed are shown to be distinct under the criteria of MPEP § 806.05(c) - § 806.05(i), the examiner, in order to establish reasons for insisting upon restriction, must show by appropriate explanation one of the following: (A) Separate classification thereof: This shows that each distinct subject has attained recognition in the art as a separate subject for inventive effort, and also a separate field of search. Patents need not be cited to show separate classification"). Thus, the Examiner's use of the classification system is proper, [5] Applicants filing fees do not prohibit the examiner from restricting an application where the Groups have been properly shown to be patentably distinct (e.g., See MPEP 802-803). In addition, contrary to Applicants' assertions that the sciences are not being adequately "promoted" by current Office policy, the Examiner notes that the USPTO has a long and distinguished career for promoting the sciences and useful arts with

over six million patents issued to date, and [6] the restriction is proper for the reasons set forth above and in the original restriction requirement and, as a result, Applicants' arguments are moot. In addition, the Examiner notes that there are two criteria set forth in the MPEP for determining whether a restriction is proper including: (A) The inventions must be independent or distinct as claimed: and (B) There must be a serious burden on the Examiner if restriction is required (see MPEP § 803), neither of which refer to "future" double patenting issues.

- 9. Applicant's election of species is also acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election of species has also been treated as an election without traverse (MPEP § 818.03(a) and/ or 37 CFR 1.111(b)).
- 10. As a result, the restriction requirement and/or election of species is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

11. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98 (b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on the form PTO-892, they have not been considered.

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Specification

12. The abstract of the disclosure is objected to because it contains more than 150 words. (See MPEP § 608.01, "Abstract of the Disclosure: A brief narrative of the disclosure as a whole in a single paragraph of 150 words or less commencing on a separate sheet following the claims").

Objections to the Claims

- 13. Claims 12-20 and 26 are objected to because of the following informalities:
 - A. For *claim 12*, the phrase "when R_7 is COR'₁₁" appears to be a typographical error because R_7 was only previously defined using an " R_{10} " notation (not an " R'_{11} "). For example, the claim defined R_7 as "a substituent attached at one of the two ring nitrogen atoms ... having the formula ... $\underline{COR_{10}}$... in which R_{10} is as above defined", which does not refer to (and/or include) the R'_{11} group. Applicants are requested to clarify and/or correct. The Examiner recommends replacing R_{11} with R_{10} to provide consistent nomenclature.
 - B. For claim 26, the word "us" has been misspelled and should read "use".
 - C. Claim 20 is missing a period. Appropriate correction is required.

Claims Rejections - 35 U.S.C. 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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14. Claims 12-20 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A. Claims 12-14 recite improper Markush format. For example, claim 12 reads "R₁ to R₄ independently represent hydrogen <u>or</u> halogen atom, hydroxyl, nitro <u>or</u> NR₈R₉ group, wherein R₈ and R₉ independently represent hydrogen <u>or</u> an optionally substituted group ... <u>or</u> unsaturated heterocyclyl group, <u>or</u> a residue of formula COR₁₀ ... in which R₁₀ is hydrogen atom or an optimally substituted group ... [etc.]." The term "or" must only be used. It is suggested to use standard Markush language; see MPEP 2173.05(h) concerning alternative expressions:

Alternative expressions are permitted if they present no uncertainty or ambiguity with respect to the question of scope or clarity of the claims. One acceptable form of alternative expression, which is commonly referred to as a Markush group, recites members as being "selected from the group consisting of A, B and C." See Ex parte Markush, 1925 C.D. 126 (Comm'r Pat. 1925).

When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if "wherein R is a material selected from the group consisting of A, B, C and D" is a proper limitation, then "wherein R is A, B, C or D" shall also be considered proper.

Here, it is not clear, for example, whether the COR_{10} is used to modify the R_8 and R_9 groups of NR_8R_9 (e.g., $NR_8R_9 = NR_8COR_{10}$) or the R_1 to R_4 substituents (e.g., $R_1 = COR_{10}$). Therefore, claims 12-14 and all dependent claims are rejected under 35 U.S.C. 112, second paragraph.

Claims Rejections - 35 U.S.C. 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

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(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 15. Claims 12-15 and 26 are rejected under 35 U.S.C. 102(a) as being anticipated by Thakare et al. (Thakare, S. S.; Doshi, A. G. "Synthesis of 3"-substituted 1H-3-(2"-hydroxyl-5"-chlorophenyl)-5-(2'-furyl)-2-pyrazoles and their derivatives" **January-March 2001**, 13(1), 237-240).

For claims 12 and 26, Thakare et al. (see entire document) disclose, for example, the methyl and phenyl esters shown on the bottom of page 239 with herbicidal activity (e.g., bottom of 265 wherein 1-(3-(4-chloro-2-hydroxyphenyl)-5-(furan-2-yl)-1Hpyrazol-1-yl)ethanone and (3-(4-chloro-2-hydroxyphenyl)-5-(furan-2-yl)-1H-pyrazol-1yl)(phenyl)methanone are disclosed when R = H; see also Introduction disclosing a variety of biological activities), which anticipate the claimed invention. In this scenario, $R_1 = H/NO_2/Br$ for compounds a/b/c, respectively; $R_{2,4} = H$; $R_3 = Cl$, which fall within the scope of hydrogen, halogen and/or nitro as defined for R_{1-4} ; $R_5 = H$; $R_6 =$ furan, which falls within the scope of heterocyclyl (e.g., see specification, page 7, lines 7-15, "The term 'heterocyclyl' as used herein refers to ... furan"); and $R_7 = C(=0)-CH_3$ (or C(=0)-Ph for the compound on the bottom right), which falls within the scope of CONHR₁₀ wherein R_{10} = alkyl or aryl. The Examiner further notes that both the methyl and phenyl esters do not fall within Applicants' proviso because R₆ is "not H, CH₃ or an optionally substituted phenyl" and thus is not prohibited from the claimed scope. For claim 26, it is also noted that a preamble is generally not accorded any patentable weight where it

merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Here, the "use as a medicament" statement occurs in the preamble and merely recites "the intended use of a structure" and thus is not afforded any patentable weight in accordance with cases like *In re Hirao* and *Kropa v. Robie*.

For *claim 13*, Thakare et al. disclose either hydrogen or halogen atoms for R1-R4 when R = a or c (e.g., see figure at bottom of page 239). In addition, the COCH₃ or COC_6H_5 groups are located meta to the hydroxylphenyl ring.

For *claim 14*, Tharkare et al. disclose a compound wherein R_2 and R_3 are selected from hydrogen and chlorine (e.g., see figure at bottom of page 239 wherein R_2 is H and R_3 is chlorine).

For *claim 15*, Tharkare et al. disclose furan for R₆ that falls within the scope of an unsaturated heterocyclyl group (e.g., see figure at bottom of page 239; see also see specification, page 7, lines 7-15, "The term 'heterocyclyl' as used herein refers to ... furan").

16. Claims 12 and 26 are rejected under 35 U.S.C. 102(b) as being anticipated by Nawwar et al. (Nawwar, G. A. M.; Haggag, B. M.; Swellam, R. H. Archiv der Pharmazie 1993, 326(1), 831-6).

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For claims 12 and 26, Nawwar et al. (see entire document) disclose, for example, compounds 9a and 9b that show molluscicidal activity (e.g., see Nawwar et al, page 326, scheme 1; see also table 1; see also Experimental section), which anticipate the claimed invention. For compound 9a, R_{1-4} = hydrogen; R_5 and R_6 = hydrogen and furan, respectively, wherein the furan falls within the scope of an unsaturated heterocycle (e.g., see specification, page 7, lines 7-15, "The term 'heterocyclyl' as used herein refers to ... furan"); and $R_7 = C(=0)$ -NH-Ph, which falls within the scope of CONHR₁₀ wherein R_{10} = aryl. For claim 26, it is also noted that a preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See In re Hirao, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and Kropa v. Robie, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). Here, the "use as a medicament" statement occurs in the preamble and merely recites "the intended use of a structure" and thus is not afforded any patentable weight in accordance with cases like In re Hirao and Kropa v. Robie.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

⁽a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

17. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

18. Claims 12-15, 17-18 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thakare et al. (Thakare, S. S.; Doshi, A. G. "Synthesis of 3"-substituted 1H-3-(2"-hydroxyl-5"-chlorophenyl)-5-(2'-furyl)-2-pyrazoles and their derivatives" **January-March 2001**, 13(1), 237-240) and Silverman (Silverman, Richard B. The Organic Chemistry of Drug Design and Drug Action. New York: Academic Press, Inc. **1992**, pages 19-23) and Nawwar et al. (Nawwar, G. A. M.; Haggag, B. M.; Swellam, R. H. *Archiv der Pharmazie* **1993**, *326(1)*, 831-6).

For *claims 12-15 and 26*, Thakare et al. teach all the limitations stated in the 35 U.S.C. 102(a) rejection above (incorporated in its entirety herein by reference), which anticipates and, as a result, renders obvious claims 12-15 and 26.

The prior art teaching of Thakare et al. differ from the claimed invention as follows:

For *claims 17-18*, the prior art teachings of Thakare et al. differ from the claimed invention by not specifically reciting the use of $R_7 = \text{CONHR}_{10}$ such as CONHC_6H_5 when $R_{10} = \text{aryl}$. Thakare et al. only disclose, for example, $R_7 = \text{COC}_6\text{H}_5$ (see Thakare

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et al., page 239, compound in bottom right corner of scheme). That is, Thakare et al. disclose a -CO- instead of the requisite -CONH-.

However, Silverman and Nawwar et al. teach the following limitations that are deficient in Thakare et al.:

For *claims 17-18*, the combined references of Silverman and Nawwar et al. (see entire documents) teach that -CONH- is commonly substituted for -CO- for the purposes of modifying the biological activity of lead compounds i.e., -CONH-/CO represents a "biosteric" substitution (e.g., see Silverman, page 19, and especially Table 2.2, element 2.b. and Table 2.3, element 1 showing -C(=O)- is a biostere of -C(=O)N-; see also Nawwar et al., scheme 1, compound 9a showing a structurally related compound with the requisite -CONH- group attached to the pyrazole ring).

It would have been prima facie obvious to one skilled in the art at the time the invention was made to substitute a -CONH- for the -CO- group of the phenylester as disclosed by Thakare et al. (e.g., see Thakare et al., page 239, compound on bottom right of the scheme) because Silverman explicitly states that this "-CONH-/-CO" substitution is commonly made in the pharmaceutical arts as a result of the common chemical and/or physical properties that these two substituents display and that similar biological properties would result from such a substitution (e.g., see Silverman, Table 2.2, element 2b and Table 2.3, element 1; see also, page 19, "Bioisosteres [i.e., -CONH-/-CO, see Table 2.3, element 1] are substituents or groups that have chemical or physical similarities, and which produce broadly similar biological properties"). One of skill in the art would have been motivated to make the substitution because it would result in

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compounds with "similar [biological] properties" (see above) that are "useful ... [in] attenuat[ing] toxicity or ... modify[ing] the activity of a lead ... [or for] the alteration of metabolism of a lead" (e.g., see Silverman, page 19). Finally, a person of skill in the art would reasonably expected to be successful because Silverman states that these substitutions are commonly made in the pharmaceutical arts (e.g., see Silverman, section 4. Bioisosterism) and Nawwar et al. provide an explicit example wherein a -CONH-group has been attached to a pyrazole on a structurally related compound (e.g., compare Nawwar et al., scheme 1, compound 9a to Thakare et al., page 239, phenylester on bottom right of scheme).

Allowable Subject Matter

19. No claims are allowed. However, claims 16, 19 and 20 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, AND if rewritten in independent form including all of the limitations of the base claim and any intervening claims to overcome the objections to being dependent upon a rejected base claim.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (571) 272-0808. The examiner can normally be reached Monday-Friday from 9:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571) 272-0811. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jon D. Epperson, Ph.D. June 20, 2005

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